GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:135
ANSWERED ON:26.02.2003
BANNED DRUGS AVAILABLE IN THE COUNTRY
BALIRAM;SUNIL KHAN

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government have taken cognizance of news reports to the effect that the drugs which have been banned abroad including Analgin and Furazolidone etc. are still being produced, stacked and sold in India;

(b) if so, the details of such drugs including their brand names;

(c) whether the drugs were banned abroad due to the serious side effects;

(d) if so, the details thereof;

(e) the measures taken/being taken by the Government to ban the production and sale of such drugs in the country; and

(f) if not, the reasons therefor?

Answer

MINISTER OF HEALTH AND FAMILY WELFARE AND PARLIAMENTARY AFFAIRS (SMT. SUSHMA SWARAJ)

(a)to(f): A Statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 135 FOR 26.2.2003

Recent newspaper reports have alleged that drugs like Analgin, Terfenadine, Astemizole, Lynestenol, Phenylubutazone, Phenolphthalein, Piperazine, Furazolidone, Nitrofurazone and Droperidol, though banned globally, are being marketed in the country .

News reports have also appeared expressing concern about the use of Nimesulide, (an anti-inflammatory, analgesic and antipyretic drug) following its suspension in some European countries. Safety aspect of this drug has been extensively evaluated in consultation with leading Orthopedicians, Gastroenterologists and Pediatricians in the country as well as the Indian Academy of Pediatricians (IAP). Medical experts have opined that the drug is safe and useful. As per orders of the Delhi High Court, this drug will be further reviewed by Drug Technical Advisory Board (DTAB).

The status of these drugs is given in Annexure.

However, these news reports are misleading. Drugs like Analgin and Furazolidone are currently used in large number of countries including many developed countries. There is no system of global banning of a drug. Certain drugs and formulations banned in some countries at times continue to be marketed in other countries. The decision to do so is normally based on risk assessment process which is influenced by a number of factors such as the disease pattern in a country, the varying reactions of certain ethnic groups in a given population to the drug and the availability of safer substitutes as well as the cost factor involved in the treatment of a particular disease. There is also the overall awareness that administration of any drug is not absolutely free from side effects or adverse reactions in a statistically insignificant minority of the population.

The risk assessment of an approved drug begins with information about its review, restriction, discontinuation or ban in any country. The evaluation of the data is done in consultation with leading experts in the given specialization. Based on their advice, the matter is placed before the Drug Technical Advisory Board (DTAB), a statutory body which comprises of representatives from the medical profession, the State drug enforcement authorities, experts institutions agencies that advise Government on technical issues related to the implementation of the Drugs and Cosmetics Act 1940, like whether or not to ban or phase out an existing drug. So far, 75 categories of drugs/drug formulations have been prohibited in the country.

ANNEXURE

LOK SABHA STARRED QUESTION NO. 135 FOR 26.2.2003 STATUS OF THE DRUGS MENTIONED IN REPORTS

S.No. Name of the Drug Status

1. Analgin — After extensive examination of its benefits-risks, ratio and the data available, experts had recommended for its continuous use except for its combination formulations with other drugs. The DTAB, therefore, did not recommend for its ban and this position was explained to Supreme Court of India in a PIL filed in 1994. The PIL has been disposed in February 2001 without any instruction to the contrary.

2. Terfenadine — Based on the recommendations of experts, that better drugs are available in this category (anti-histaminic), the sale of this drug will be stopped by 31st March 2003. This drug is in use in some countrie

3. Astemizole — The drug was reviewed in 1993 and continued marketing with label warning ` Not to exceed 10 milligram daily dose` was allowed. The drug was again reviewed. It has been decided to stop its sale in India by 31st March 2003. This drug is in use in some countries.

4. Lynestrenol — The drug has been reviewed by experts during early 90`s and its continued marketing is considered appropriate for menstrual disorders.

5. Phenylbutazone — The drug had been examined by the expert in the context of doses used in India and overall benefit-risk and recommended use in short term inflammatory disorders and for ankylosing spondylitis. The drug is permitted as a single drug formulation. However, its combinations with other drugs have been banned. This position was placed before the Supreme Court of India.

6. Phenolphthalein — The drug continue to appear in British and India Pharmacopoeia as Laxative. Review is however, proposed to be undertaken in next sub-committee meeting in March 2003.

7 Piperazine — The drug was examined by experts during 1992- 93 and was considered a cheap and effective drug for treatment of roundworms. This position was also placed before Supreme Court of India.

8. Furazolidone — Examined by experts in early nineties and considered effective for treatment of gastroenteritis in the Indian context. The drug is permitted as a single drug formulation. However, its use in combination formulation has been prohibited in India. This position was also placed before the Supreme Court.

9. Nitrofurazone — Examined by experts during early nineties. Used as Topical cream and was considered useful for superficial wounds, burns and skin infections. The drug is permitted as a single drug formulation. However, its use in combination formulation has been prohibited in India.

10. Droperidol — As per the information available the drug is used as adjunct to Anesthesia in few countries. As per WHO new letter No. 1, 2002, USFDA has directed for warning and precautions on the labeling.

11 Cerivastatin — The drug was introduced in the country in year-2000 and was later withdrawn in 2001. No new permissions are being granted. Therefore, the drug is not presently marketed in the country.

12. Nimesulide — A non-steroidal anti-inflammatory drug reported to be use in about 50 countries including India and is indicated for acute pain/inflammation and fever.Considering the media reports and suspension the use of Nimesulide in Finland, Turkey and Spain, a detailed examination is undertaken by an expert committee to deliberate on the issues concerning safety of Nimesulide, including its use in children. Majority of expert have confirmed the reliability of Nimesulide and no serious adverse reaction have

been reported in the country.

13. Quiniodochlor(Clioquinol, Iodoclorhydroxyquinoline)

This drug has been used for the treatment of intestinal amoebiasis and traveller`s diarrhea etc. In 60s sub acute mylo-opticoneuropathy (SMON) was reported in Japan and the drug was withdrawn in many countries for oral use. However, the safety and efficacy of this drug was extensively examined by medical experts in India and considering its usefulness and local needs it was opined to allow its continued marketing in India. There have been no reports of SMON effect in Indian population.

The drug is also used for local applications as an antibacterial in almost all countries. This clarification had also been filed in the Supreme Court in the matter of a PIL filed by Drug Action Forum and the explanation has been accepted.